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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,193	SEGAL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/19/03, 04/19/04, + 07/05/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-16* is/are rejected.

7)☒ Claim(s) *1-8 and 10-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/27/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of:

a method of modulating an immune response in an animal comprising the administration of a composition to said animal, wherein the composition comprises a cell and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a cell-surface binding moiety and a second amino acid sequence comprising a ligand for a cell surface polypeptide; wherein the elected cell is a mammalian cell, the ligand is a ligand for a cytokine receptor, wherein the cytokine is GM-CSF;

in the reply filed on 07/05/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Additionally, Applicant is reminded that the restriction requirement issued 02/17/2005 is a restriction among multiple patentably distinct inventions, not an election of species.

Status of Claims

3. Claims 1-16 are pending. Claim 9 is withdrawn from examination because the claim is directed to a ligand for CD40, and not a ligand for a cytokine receptor as elected. Claims 1-8 and 10-16 are under examination.

Specification

4. The abstract of the disclosure is objected to because the disclosure provides two different abstracts. It is not readily apparent if the abstract provided on page 201 or page 976 of the disclosure is the preferred abstract for the claimed invention. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The term "effector" is misspelled as "effeector" in last sentence, last paragraph, page 1 of the disclosure. Appropriate correction is required.

Claim Objections

6. Claims 1-8 and 10-16 are objected to because of the following informalities: the recitation "a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte" is objected. In the instant, the recitation is awkwardly presented. It is believed that the intended meaning of the recitation is "a second amino acid sequence comprising the amino acid sequence of a ligand for a cell surface polypeptide of a leukocyte". However, as presented, the recitation does not immediately transmit such intention.

7. Additionally, claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 12 recites a dependency to claim 11. Claim 11 requires the cell to be pathogenic; however, claim 12 requires the cell to be attenuated. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-8 and 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "further comprises some of said polypeptide which is not bound to said cell" renders the claims indefinite. It is not clear what "some" encompasses. The term "some" is imprecise. It is unclear how much of the polypeptide is considered as "some" and which portion of the polypeptide is covered by "some". Therefore, it renders the claims indefinite.

Additionally, the recitation "at least about" in line 1 of claim 8 also renders the claim indefinite. It is unclear as to what range of specific activity is covered by the term "about" in the recitation "at least about". For the purpose of a prior art search, the cited recitation is substituted with the recitation "at least".

Furthermore, the recitation "modulating an immune response" also renders the claims indefinite. In the instant, it is unclear what kind of immune response is being modulated, and what type of modulation. Is it the humoral and/or cellular immune response being modulated? Is it B cell and/or T cell responses being modulated? Is

the modulation directed at the stimulation, suppression or elimination of an immune response? It intended to provide a more or less efficient immune response? Or is it more or less rapid immune response?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant rejection is targeted at the limitation recited in claim 8.

The claim requires the second amino acid sequence having at least five contiguous amino acids of a naturally occurring cytokine, specifically GM-CSF.

It is recognized from teachings that are primarily provided in the specification and the art that the cytokine is the active component that provides the adjuvant activity.

Thus, the claim is drawn encompass second amino acid sequence having at least five contiguous amino acids of a naturally occurring GM-CSF, and function as an adjuvant. In the instant, the requirement is directed at a genus of polypeptides that is defined only by sequence identity and a function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number

of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include:

- disclosure of complete or partial structure,
- physical and/or chemical properties,
- functional characteristics,
- correlation between structure and function, and
- methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice:

In the instant, the specification only teaches of the full GM-CSF polypeptide. The specification does not teach of a single amino acid sequence that is less that full GM-CSF polypeptide. Ergo, the specification does not provide for sufficient number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics:

- disclosure of complete or partial structure: While the complete structure of the naturally occurring GM-CSF polypeptide is not

provided in the specification, a complete structure of the polypeptide can be readily ascertain from the art. However, no partial structures of the GM-CSF polypeptide are provided in the specification, not to mention those that can be use as an adjuvant.

- physical and/or chemical properties: The only two physical and/or chemical properties that are provided in the specification is that the second amino acid is required to have at least 5 contiguous amino acids of GM-CSF.
- functional characteristics: From the disclosure and the art, it is gathered that the second amino acid sequence is the active component that provides the adjuvant activity.
- correlation between structure and function: The specification does not provide a correlation between the required or expected functional characteristic and the structure that is responsible for the required or expected functional characteristic.
- methods of making the product: Beside the complete GM-CSF polypeptide, the specification does not disclose of method of making any second amino acid sequences that comprises at least 5 contiguous amino acid sequences of GM-CSF, not to mention those that can be use as an adjuvant.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the chemical structure of the second amino acid sequence that is used as an adjuvant in the claimed invention, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making the second amino acid sequence. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the complete sequence of GM-CSF, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-4, 6-8, 10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbage et al.,[1] in view of Galili et al.[2]

The claims are directed to the administration of a composition comprising a cell that is bound to a multifunctional molecule, wherein the molecule comprises i) a first amino acid sequence that comprises a cell-surface binding moiety, and ii) a second amino acid sequence, whereby the second amino acid sequence is a ligand for a cell surface polypeptide of a leukocyte to a animal to modulate an immune response.

The claim later define the multifunctional molecule as a fusion polypeptide, wherein the first amino acid sequence is C-terminal to said second amino acid sequence.

The claims later limit i) the animal to a mammal, which is further limited to a human; ii) the ligand to a) a ligand for a cytokine receptor and b) to comprise at least 5 contiguous amino acids of a naturally occurring GM-CSF; iii) the cell to a pathogenic cell, attenuated cell, and cells that are unable to divide; and iii) the leukocyte be an antigen presenting cell, or a professional antigen presenting cell, which is further limited to a dendritic cell.

Burbage et al. teaches a composition comprising a fusion polypeptide.

Burbage et al. teaches a fusion polypeptide, wherein the polypeptide comprises i) a first amino acid sequence, and ii) a second amino acid sequence that is a ligand for a

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[1] Burbage et al. Ricin fusion toxin targeted to the human granulocyte macrophage colony stimulating factor receptor is selectively toxic to acute myeloid leukemia cells. Leukemia Research, 1997, Vol. 21 NO. 7, 681-690.

[2] Galili et al. Cutting edge communication: Preparation of autologous leukemia and lymphoma vaccines expressing alpha Gal epitopes. Journal of Hematotherapy and Stem Cell Research, 2001, Vol. 10, 501-511.

cell surface polypeptide of a leukocyte. The first amino acid sequence used by Burbage et al. is ricin. Ricin is a lectin. The ricin polypeptide use by Burbage et al. is noted to be capable of binding to a carbohydrate; ergo, it comprises a carbohydrate-binding domain, which are present on cells. Thus, the first amino acid sequence provided by Burbage et al. comprises a cell-surface binding moiety. [Title; and 1st full paragraph, left column of page 682]

The ligand that Burbage et al. teaches is GM-CSF. GM-CSF is a ligand for a cytokine receptor--GM-CSFR, which is a cell surface polypeptide of an antigen presenting cell, a professional antigen presenting cell, particularly dendritic cell.

Additionally, since Burbage et al. uses the GM-CSF polypeptide, the polypeptide would necessarily have at least five contiguous amino acids of a naturally occurring GM-CSF. Thus, Burbage et al. teaches a second amino acid sequence that is a ligand for a cell surface polypeptide of a leukocyte, and have at least 5 contiguous amino acids of a naturally occurring GM-CSF.

In the instant, Burbage et al. teaches the use of fusion polypeptide to target cancer cells to provide a form of cancer treatment. However, Burbage et al. does not teach the administration of the fusion polypeptide with a cell to an animal, a mammal or a human. Additionally, the fusion polypeptide of Burbage et al. is noted to have the following structural order: the first amino acid sequence is C-terminal to the second amino acid sequence. [Abstract.]

However, Galili et al. teaches the use autologous cancer cells to induce an antitumor immune response. [Page 501 to first full paragraph, left column on page 501]

Specifically, Galili et al. teaches the use of attenuated (irradiated) tumor cells. [Item No. 2 on page 508]

In the instant, both Burbage et al. and Galili et al. are interested in providing an antitumor response. Thus, it would have been prima facie obvious for one of ordinary skill in the art the time the invention was made to combine the teachings of both Burbage et al. and Galili et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to make a composition having optimal antitumor immune response. Furthermore, one of ordinary skill in the art at the time the invention was made would have been motivated to administer that composition to a subject (human) that is diagnosed with a cancer or having a tumor to treat the subject of the cancer or tumor, wherein the administration of the composition would necessarily modulate the subject's immune system. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Burbage et al. teaches the use of an fusion polypeptide to target cancer cells, and Galili et al. teaches the use of attenuated tumor cells to provide an antitumor immune response.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbage et al., in view of Galili et al., as applied to claims 1 and 4, in further view of Meyers et al.[3]

The claim requires the first amino acid sequence be N-terminal to the second amino acid sequence.

The significance of Burbage et al. and Galili et al. as it pertains to claims 1 and 4 is provided above.

Neither Burbage et al. nor Galili et al. teaches the structural orientation of the amino acid sequences as claimed.

As stated above, the fusion polypeptide of Burbage et al. has the following structural order: the first amino acid sequence is C-terminal to the second amino acid sequence. [Abstract.]

However, the art recognizes that a fusion polypeptide having the structural order: the first amino acid sequence is N-terminal to the second amino acid sequence as an equivalent alternative to a fusion polypeptide having the reverse structural order, as evidenced by Meyers et al. [Lines 40-67, column 22] Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made use a fusion polypeptide having the reverse structural order as that provided by Burbage et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because both fusion polypeptides are recognized in the art as equivalent substitutes for one another.

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[3] Meyers et al. U.S Patent No. 6911317.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbage et al., in view of Galili et al., as applied to claims 1.

The claim requires that the cell be pathogenic.

The significance of Burbage et al. and Galili et al. as it pertains to claims 1 is provided above.

Neither Burbage et al. nor Galili et al. teaches the use of a pathogenic cell to administer to a mammal.

However, the use of autologous tumor cells (pathogenic cells) have been viewed in the art as potentially one of the best sources for treatments directed against the metastasizing tumors, as evidenced by Galili et al. [2nd full paragraph of page 502]

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer a pathogenic tumor cell to a subject. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to treat the subject of metastasizing tumors. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the art recognizes the importance of pathogenic cells in providing treatment against metastasizing tumors.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations “cell” and “antigen bearing target”.

However, the recitation “cell” does fall entirely within the scope of the recitation “antigen bearing target”. Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations “first amino acid sequence which can bind to a carbohydrate” and “first amino acid sequence comprising a cell-surface binding moiety”.

However, carbohydrate is a cell-surface binding moiety. Ergo, it would have been prima facie obvious for one on ordinary skill in the art at the time the invention was made to use a carbohydrate binding domain as cell surface binding moiety.

Additionally, the last difference between the two claims is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/666886.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/645000.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule.

The difference between the two claims is the recitations “cell” and “antigen bearing target”.

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence which can bind to a carbohydrate" vs. "first amino acid sequence comprising a cell-surface binding moiety".

However, a carbohydrate is a cell-surface binding moiety. Ergo, it would have been prima facie obvious for one on ordinary skill in the art at the time the invention was made to use a carbohydrate binding domain as cell surface binding moiety.

Another difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule."

However, the ligands recited in claim 1 of the conflicting patent applications are all ligands for a cell surface polypeptide of a leukocyte. In the instant, claim 1 of the conflicting patent application falls entirely within the scope of claim 1 of the examined claimed. Hence, claim 1 of the conflicting patent application anticipates this aspect of the claim 1 of the instant patent application.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/224661, in view of Wortham et al. [4] and Faulkner et al.[5]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The

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[4] Wortham et al. Enhanced protective antibody responses to PspA after intranasal or subcutaneous injections of PspA genetically fused to granulocyte-macrophage colony-stimulating factor or interleukin-2. Infection and Immunity, 1998, Vol. 66, No. 4, 1513-1520.

[5] Faulkner et al. IL-2 linked to a peptide from influenza hemagglutinin enhances T cell activation by affecting the antigen-presentation function of bone marrow-derived dendritic cells. International Immunology, 2001, Vol. 13, No. 6, 713-721.

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

The difference between the two claims is the recitation "a first amino acid sequence comprising a cell-surface binding moiety" and "lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin".

However, the lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence comprising a cell-surface binding moiety.

The other difference between the two claims is the recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a naturally occurring GM-CSF molecule".

However, the naturally occurring GM-CSF molecule is the second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898 , in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations “first amino acid sequence comprising a cell-surface binding moiety” and “carbohydrate binding domain”.

However, a carbohydrate binding domain is encompassed by the generic recitation “first amino acid sequence comprising a cell-surface binding moiety”.

The other difference noted between the two claims is the recitations “second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte” and “a ligand for a cell surface polypeptide”.

However, the “a ligand for a cell surface polypeptide” is encompassed by the generic recitation “second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte”.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-147 of copending Application No. 10/666885, in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vector comprising a nucleic acid molecule composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations “first amino acid sequence comprising a cell-surface binding moiety” and “carbohydrate binding domain”.

However, a carbohydrate binding domain is encompassed by the generic recitation “first amino acid sequence comprising a cell-surface binding moiety”.

The other difference noted between the two claims is the recitations “second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte” and “a ligand for a cell surface polypeptide”.

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a vector construct comprising a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to place the vector expression construct in a cell to express/make the fusion polypeptide. Furthermore, it would have been prima facie obvious for one of ordinary skill in the art to administer the construct to a subject because the art teaches that the administration of a cytokine construct enhance humoral as well as cell-mediated responses. [page 1513 of Wortham et al.]

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 10/666871, in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations “first amino acid sequence comprising a cell-surface binding moiety” and “carbohydrate binding domain”.

However, a carbohydrate binding domain is encompassed by the generic recitation “first amino acid sequence comprising a cell-surface binding moiety”.

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at the administration of a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to administer the construct to a subject because the art teaches that the

administration of a cytokine construct enhance humoral as well as cell-mediated responses. [page 1513 of Wortham et al.]

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/666834, in view of Wortham et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide. And the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application requires the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen; whereas claim 1 of the instant patent application does not require the same.

However, the antigen bearing target of claim 1 of the instant patent application is generic to the an antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen of claim 1 of the conflicting patent application.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/6667166 in view of Wortham et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/6668073.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

27. No claim is allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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